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SEP 23 2003

Applicant(s): Davis et al.

Application No.: 09/944,389

Filed: 9/4/2001

Title: Analytical Test Device and Immuno
Assays and Methods of Using Same

Attorney Docket No.: IMIN.P-002-2

Customer No.: 021121

Group Art Unit: 1641

Examiner: Bao-Thuy Nguyen

Confirmation No: 9864

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

RESPONSE TO OFFICIAL ACTION

Dear Sir:

This is in response to the Office Action mailed June 20, 2003 for the above-captioned application. Reconsideration and further examination are respectfully requested.

The Examiner has stated that claim 87, 88, and 96-1-02 are drawn to a different invention than that previously considered, and has therefore stated that they are withdrawn from consideration. Applicants respectfully point out, however, that these claims are generic with respect to the claims previously considered, since they do not require the presence of the housing, but also do not preclude its presence. As such, Applicants submit that the claims are not properly considered as a distinct invention and requests that these claims be considered in this application.

I hereby certify that this paper and any attachments named herein are transmitted to the United States Patent and Trademark Office, Fax number: 703 308 4242 on September 22, 2003.

Marina T. Larson
Marina T. Larson, PTO Reg. No. 32,038

September 22, 2003
Date of Signature

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The Examiner asserts that claims 93 and 94 do not comply with the written description requirement. Claims 93 and 94 read as follows:

✓ 93. The device of claim 84, wherein the macroporous body and the porous carrier each have two major surfaces and wherein the flow path is substantially planar and parallel to the major surfaces of macroporous body and the porous carrier.

94. The device of claim 93, wherein the macroporous body and the porous carrier overlap at their adjacent ends.

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Applicants respectfully direct the Examiner's attention to elements 113 and 114 in Fig. 1, which are the macroporous body and carrier, respectively. Both are flat on the top and bottom, and thus have two major surfaces. The flow runs through the macroporous body 113 and into the carrier 114. The flow path is substantially planar since there are no major changes in direction, and it is parallel to the top and bottom of the major surfaces of the macroporous body and carrier. Further, the adjacent ends of the macroporous body and the carrier are shown to overlap in the figure. Thus, Applicants submit that claims are supported by the specification as filed and that the rejection should be withdrawn.

The Examiner rejected claims 26, 27, 29, 30, 32-36, 39-46, 48, 49, 51-55, 58-63, 84-86, 89, 91, 9 and 95 as anticipated by Eisinger. In support of this rejection, the Examiner asserts that Eisinger teaches that diffusible particulate label is disposed in the pad 110. The Examiner cites Col. 5, lines 28-36 as showing this. However, this teaching does not appear at the location identified by the Examiner which states only that

The first member binds, in the indicator zone, to the second member, and the resulting bound complex is detected. Detection may use any of a variety of labels and/or markers, e.g., enzymes, radioisotopes, liposomes, fluorescent tags, polymer dyes, or colored particles, etc., and detection is by means of, for example, direct visual observation, by developing a color, by radioactive isotope counting, by fluorescence measurement, or by any of many other techniques by which the presence or absence of a chemical or biochemical species may be detected directly or indirectly.

This says how the bound complex is detected, but it says nothing about the location of the diffusible label in the unused device. Furthermore, Applicants find no other teaching that shows or suggests that a particulate label is ever disposed in the pad 110.

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At Col. 11, lines 14-23, Eisinger states that:

In the particular apparatus shown, pad or disc 110 may be used as a source of supplementary reagent. The disc may also be a non-bibulous membrane or may be a liquid absorbent, such as filter paper. For example, in an ELISA assay, disc 110 may contain enzyme-labeled antibody, which dissolves in the sample and couples with an analyte antigen. The complex is then retained in the indicator zone by additional antibody capable of binding the analyte-enzyme labelled complex which is formed.

This, however, shows only that some reagents, and in particular soluble enzyme-label antibody, may be disposed in the pad 110. It does not state that this is the location for all reagents. That pad or disc 110 is not necessarily the location of the reagents is reiterated in at Col. 12, lines 1-6 of Eisinger, which read:

The disc 110 in addition to **or instead of carrying a reagent**, can act as a filter for the application zone 102 of the membrane 100 removing large particles from the sample. The disc is, however, optional. The liquid sample is introduced to the pad 110 or directly to the zone 102 by a pipette, dropper or other device.

Furthermore, the teaching of Eisinger with respect to detectable particles indicates only that they are applied to the application zone before or with the sample, i.e.,

the sample modified to contain detectable particles is applied at the application zone and flows laterally through the indicator zone. In an alternative, the particles can be added subsequent to sample. In another alternative, the particles could be impregnated into the application zone during manufacture. For example, latex beads could be lyophilized in place in the application zone.

Col. 18, lines 28-39. Since the disc 110 is optional, and intended to act as a filter to trap particles when present, there is neither a teaching nor a suggestion that this disc 110 should contain the particles.

For these reasons, Applicants submit that the rejection claims are not anticipated by Eisinger. Accordingly, the rejection should be allowed.

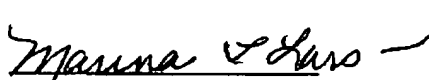
The Examiner also rejected claims 28, 31, 37, 38, 47, 50, 56, 57, 64-83, 90, 93 and 94 as obvious over the combination of Eisinger, May and Olsen. This rejection depends on the flawed analysis of Eisinger however. The Examiner has not argued that anything in the

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secondary references would suggest modifying the teaching of Eisinger in a way that would lead to placing a particulate label in the disc 110. Thus, for the same reasons as discussed above, this rejection should be withdrawn.

In view of the foregoing, Applicants submit that all claims are now in form for allowance. Favorable reconsideration is respectfully urged.

Respectfully submitted,



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